MAR - 8 2001

K010426

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

ProPort™ Systems Pre-assembled with Silicone Catheter

February 9, 2001

I. GENERAL INFORMATION

Applicant's Name and Address:	SIMS Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Lisa Stone Manager, Regulatory Affairs
Common/Usual Name:	Subcutaneously Implanted Intravascular Infusion Port and Catheter
Proprietary Name:	ProPort™ Plastic Venous Implantable Access Systems Pre-assembled with Silicone Catheter
Equivalence Device Comparison:	ProPort™ Plastic Venous Implantable Access Systems (manufactured by SIMS Deltec) PORT-A-CATH® II Venous Implantable Access Systems Pre-assembled with Polyurethane Catheter (manufactured by SIMS Deltec)

II. DEVICE DESCRIPTION

ProPort™ Plastic Venous Implantable Access Systems Pre-assembled with Silicone Catheter consist of a plastic portal (standard or low profile configuration) pre-assembled with a silicone catheter, PORT-A-CATH® access needle, and vein pick. The systems will be made available with and without introducer sets.

III. INTENDED USE OF DEVICE

A ProPort™ Plastic Venous Implantable Access System Pre-assembled with Silicone Catheter is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

IV. DEVICE COMPARISON

	PROPORT™ SYSTEMS PRE-ASSEMBLED WITH SILICONE CATHETER	**PROPORT™ SYSTEMS WITH SILICONE CATHETER**	**PORT-A-CATH® II SYSTEMS PRE-ASSEMBLED WITH POLYURETHANE CATHETER**
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	SIMS Deltec, Inc.
INDICATIONS FOR USE	A system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.	A system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.	A system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.
PORTAL MATERIALS			
Housing	Acetal Homopolymer	Acetal Homopolymer	Polysulfone/Titanium
Septum	Silicone	Silicone	Silicone
PORTAL DIMENSIONS – STANDARD SIZE (Nominal)			
Height	14.0 mm	14.0 mm	14.7 mm
Portal Base	30.5 mm	30.5 mm	30.5 mm
Septum Diameter	12.7 mm	12.7 mm	11.4 mm
PORTAL DIMENSIONS – LOW PROFILE SIZE (Nominal)			
Height	10.0 mm	10.0 mm	11.5 mm
Portal Base	25.0 mm	25.0 mm	25.0 mm
Septum Diameter	10.5 mm	10.5 mm	9.5 mm
CATHETER MATERIAL	Silicone	Silicone	Polyurethane
CATHETER DIMENSIONS (Nominal)			
I.D.	1.0 mm	1.0 mm	1.0 mm
O.D.	2.8 mm	2.8 mm	1.9 mm
Length	76 cm	76 cm	76 cm
PRE-ASSEMBLED SYSTEM	YES	NO	YES

V. SUMMARY OF STUDIES

A. Functional Testing

Catheter to portal connection testing, system pressure testing, and system clearance testing was conducted in accordance with the FDA "Guidance on 510(k) Submissions for Implanted Infusion Ports," dated October 1990.

Biocompatibility testing was conducted on system components.

B. Clinical Studies

Clinical studies were not deemed necessary regarding ProPort™ Systems Pre-assembled with Silicone Catheter due to their similarity in materials, design and function to current SIMS Deltec systems.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the ProPort™ Systems Pre-assembled with Silicone Catheter function according to specifications and the materials used in the systems are biocompatible. Therefore, these systems are considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

Ms. Lisa J. Stone
Manager of Regulatory Affairs
Sims Deltec, Incorporated
1265 Grey Fox Road
Saint Paul, Minnesota 55112

Re: K010426
Trade Name: ProPort™ Plastic Venous Implants Access Pre-assembled with Silicone Catheter
Regulatory Class: II
Product Code: LJT
Dated: February 9, 2001
Received: February 13,2001

Dear Ms. Stone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010426

Device Name: ProPort™ Plastic Venous Implantable Access Systems Pre-assembled with Silicone Catheter

Indications for Use:

"A system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucuzzella

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010426

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)